REMARKS

Present Status of the Application

The Final Office Action dated December 05, 2008 objected the specification for informalities. Claims 9-16 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

Claims 9 and 12 have been amended for clarification. The specification has been amended for correcting informalities. It is believed that the amendments are supported by the original specification and drawings of this application and can overcome the objections. After entering the amendments and considering the following discussions, a notice of allowance is respectfully solicited.

Discussion for the objections

The specification was objected as containing embedded hyperlink of browser-executable form.

The specification has been amended to remove the hyperlink (the underline) of the website.

Entry of the amendments to the specification is respectfully requested.

Discussion of 112 rejections

Claims 9-16 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

The Office Action is of the opinion that the specification showed increased risk for graft vs host disease (GvHD), rather than all rejection responses occurring after transplantation or the host-versus-graft diseases. In addition, the Office Action considered "diagnosis and/or prognosis" including patient's pretreatment and concluded the correlation cannot be observed.

Claim 9 or 12 has been amended to be "Method for predicting the likelihood of an incidence" of a disease and the disease be limited as "graft versus host diseases". The supporting grounds can be found at least in claims 5 & 12 and page 1, lines 26-27, page 8, lines 5-8 of the specification.

For clarification purposes, it is noted that claims 9 and 12 have been amended by using the term "predicting the likelihood of an incidence of ....", instead of "prognosis and/or diagnosis ...".

In fact, one or more possible pretreatments of the patients undergoing transplantation are not an obstacle for the validity of the test of the present application. First, it is unlikely that a patient in need of transplantation hasn't undergone any (symptomatic) pretreatment at all. The data presented in the present application do not differentiate according to the types of pretreatments for the patients. Hence, the correlation of the presence of any of these polymorphisms with such a rejection response disclosed herein refers to a total of patients notwithstanding any pretreatment. The test still shows a significant correlation, better than many

customary test methods in the medical field. It is inappropriate to expect the claimed method with 100% accuracy or power.

Regarding the reference Holler or Granell, gastrointestinal decontamination and/or T-cell depletion are carried out with the objective to reduce the risk of a rejection response, and being effective methods, consequentially must influence the course and therewith the prognosis of a rejection response. Thus, even if considering being cited against the prognosis significance for the outcomes of GvHDs, as asserted by the Office Action, the reference Holler or Granell should not be cited against the validity of the test or the predicting methods for the likelihood of the incidence of GvHDs as claimed now in the present application. In addition, as taught by the reference Holler (p. 4192, column 1, paragraph 2)"... NOD2/CARD15 remained a significant risk factor for GvHD and overall TRM in the subgroups.", such statement rather supports the predicting methods recited in our amended claims.

Furthermore, to any artisan in this field or any medical practitioner, the sequence of the transplantation procedures does not allow an interference of the biasing treatments as discussed in the reference Holler or Granell. A gastrointestinal decontamination and/or T-cell depletion are performed when the patient is undergoing preparation for an imminent transplantation. However, the claimed predicting method is to be performed in the forefront of a transplantation to assess the compatibility of a particular donor organ with a particular recipient and thus helps to reach a better matching of donor and recipient.

As discussed above, the disclosure of the present application meets the enablement requirement for the amended claims.

Accordingly, withdrawal and reconsideration of these 112 rejections are respectfully requested.

CONCLUSION

For at least the foregoing reasons, it is believed that the pending claims 9-16 of the present application patently defines over the prior art and are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

Respectfully submitted,
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